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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/314,919 | 05/19/99 | MICHEL | W 6464 |

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QM12/0120

EXAMINER

CHENEY, K

ART UNIT

PAPER NUMBER

3762

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DATE MAILED:

01/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/314,919

Applicant(s)

MICHEL ET AL.

Examiner

Kelly M Cheney

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☒ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 5/20/98. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the test sensor in claims 4 & 12 and the microdialysis probe in claims 9 & 14 must be shown or the feature(s) canceled from the claim(s).

No new matter should be entered.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 20. Correction is required.

Specification

4. The disclosure is objected to because of the following informalities:

Page 8, lines 13 & 16: port body 3 should be port body 10.

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites a method for analyzing body fluids, but no method steps are included.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6, 8, 10-13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ensminger et al (5281199). Ensminger et al discloses a permanently implantable access device comprising, a port body (72) implanted subcutaneously, providing for the delivery of substances and for the removal of body fluids for analysis, a shaft section (80), a mounting platform (98) that is generally disc-shaped, a valve (84) that is self closing, two tubes (94, 96) extending into the interior of the body that serve as a feed tube and an aspiration tube, catheters received into said

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tubes, and a sensing device inserted into the interior of the body via the port body. (See Figs. 3-6, 1:21-28, 1:50-57, 3:58-4:3, 8:61-9:2, & 9:43-10:21).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ensminger et al in view of Patsalos et al (5607390). Ensminger et al disclose all the elements of the applicant's invention except for the microdialysis probe. Patsalos et al disclose a microdialysis probe that can be left inside the body for an extended period of time for continuous testing and that can be positioned in different locations inside the body for fluid analysis wherein body fluids can be withdrawn. Ensminger et al discloses the use of sensing and physiological measuring devices in combination with their access device. The microdialysis probe disclosed by Patsalos et al is a physiological measuring device that is inserted into a cannula or access device. It would have been obvious to one of ordinary skill at the time of the applicant's invention to use Patsalos et al's microdialysis probe in combination with Ensminger et al's access device for analyzing body fluids.

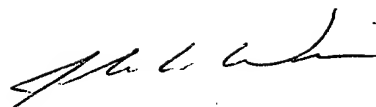
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelly M. Cheney whose telephone number is (703) 306-5444.

Application/Control Number: 09/314919

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kmc

kmc
January 12, 2000

A handwritten signature in dark ink, appearing to be "J. L. White", written in a cursive style.